

## PATENT COOPERATION TREATY

## PCT

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

REC'D 29 DEC 2006

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|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------|-----------------------|
| Applicant's or agent's file reference<br>59582-PCT                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | <b>FOR FURTHER ACTION</b>                                                    |                                                                                                             | See Form PCT/IPEA/416 |
| International application No.<br>PCT/US04/31967                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | International filing date (day/month/year)<br>28 September 2004 (28.09.2004) | Priority date (day/month/year)<br>28 September 2003 (28.09.2003)                                            |                       |
| International Patent Classification (IPC) or national classification and IPC<br>IPC: C07H 21/04 (2006.01)<br>USPC: 536/23.1,24.1,24.2                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                                              |                                                                                                             |                       |
| Applicant<br>GOVERNMENT OF THE UNITED STATES OF AMERICA, AS REPRESENTED BY THE SECRETARY, DEPARTMENT OF HEALTH AND HUMAN SERVICES                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                              |                                                                                                             |                       |
| <p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 6 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> (sent to the applicant and to the International Bureau) a total of ___ sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p> |                                                                              |                                                                                                             |                       |
| <p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the report</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input checked="" type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                                              |                                                                                                             |                       |
| Date of submission of the demand<br>04 March 2005 (04.03.2005)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                                              | Date of completion of this report<br>20 October 2006 (20.10.2006)                                           |                       |
| Name and mailing address of the IPEA/ US<br>Mail Stop PCT, Attn: IPEA/US<br>Commissioner for Patents<br>P.O. Box 1450<br>Alexandria, Virginia 22313-1450<br>Facsimile No. (571) 273-3201                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                                                              | Authorized officer<br><i>Valerie Bell-Harris</i><br>Nicole E. Kinsey, Ph.D.<br>Telephone No. (571) 272-1600 |                       |

Form PCT/IPEA/409 (cover sheet)(April 2005)

# INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/US04/31967

## Box No. I Basis of the report

1. With regard to the **language**, this report is based on:

- ☒ the international application in the language in which it was filed.
- ☐ a translation of the international application into English, which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
- ☐ publication of the international application (under Rule 12.4(a))
- ☐ international preliminary examination (under Rules 55.2(a) and/or 55.3(a))

2. With regard to the **elements** of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

- ☒ the international application as originally filed/furnished
- ☒ the description:  
 pages 1-34 as originally filed/furnished  
 pages\* NONE received by this Authority on \_\_\_\_\_  
 pages\* NONE received by this Authority on \_\_\_\_\_
- ☒ the claims:  
 pages 35-43 as originally filed/furnished  
 pages\* NONE as amended (together with any statement) under Article 19  
 pages\* NONE received by this Authority on \_\_\_\_\_  
 pages\* NONE received by this Authority on \_\_\_\_\_
- ☒ the drawings:  
 pages 1/8-8/8 as originally filed/furnished  
 pages\* NONE received by this Authority on \_\_\_\_\_  
 pages\* NONE received by this Authority on \_\_\_\_\_
- ☒ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, Nos. \_\_\_\_\_
- ☐ the drawings, sheets/figs \_\_\_\_\_
- ☐ the sequence listing (*specify*): \_\_\_\_\_
- ☐ any table(s) related to the sequence listing (*specify*): \_\_\_\_\_

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, Nos. \_\_\_\_\_
- ☐ the drawings, sheets/figs \_\_\_\_\_
- ☐ the sequence listing (*specify*): \_\_\_\_\_
- ☐ any table(s) related to the sequence listing (*specify*): \_\_\_\_\_

\* If item 4 applies, some or all of those sheets may be marked "superseded."

# INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

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## Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application

☒ claims Nos. 4-21 and 24-71

because:

☐ the said international application, or the said claim Nos. \_\_\_\_\_ relate to the following subject matter which does not require an international preliminary examination (*specify*):

☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 4-21 and 24-71 are so unclear that no meaningful opinion could be formed (*specify*):

Please See Continuation Sheet

☐ the claims, or said claims Nos. \_\_\_\_\_ are so inadequately supported by the description that no meaningful opinion could be formed (*specify*):

☐ no international search report has been established for said claims Nos. \_\_\_\_\_

☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

☐ furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Preliminary Examining Authority in a form and manner acceptable to it.

☐ furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Preliminary Examining Authority in a form and manner acceptable to it.

☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13ter.1(a) or (b) and 13ter.2.

☐ a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-bis of the Administrative Instructions, and such tables were not available to the International Preliminary Examining Authority in a form and manner acceptable to it.

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

☐ See Supplemental Box for further details

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.  
PCT/US04/31967**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. Statement**

|                               |                           |     |
|-------------------------------|---------------------------|-----|
| Novelty (N)                   | Claims <u>22, 23</u>      | YES |
|                               | Claims <u>1-2</u>         | NO  |
| Inventive Step (IS)           | Claims <u>22, 23</u>      | YES |
|                               | Claims <u>1-3</u>         | NO  |
| Industrial Applicability (IA) | Claims <u>1-3, 22, 23</u> | YES |
|                               | Claims <u>NONE</u>        | NO  |

**2. Citations and Explanations (Rule 70.7)**

Claims 1-2 lack novelty under PCT Article 33(2) as being anticipated by Saiga et al. (U.S. Patent No. 6,090,783). Saiga et al. discloses a gene expression vector comprising a) a promoter, which can be the HIV 5'-LTR, wherein the activity of the promoter is dependent on HIV Tat (see col. 4, lines 4-5; col. 8, lines 57-65; and col. 24, line 63 to col. 25, line 17), b) at least one splice donor site and at least one splice acceptor site (see figure 9 and col. 24, line 63 to col. 25, line 17), c) an expressible non-wild type HIV sequence (e.g., a therapeutic gene) located between the splice donor and splice acceptor (see col. 4, lines 6-9 and col. 8, line 66 to col. 9, line 17), and d) an RRE from HIV (see col. 9, lines 18-28), wherein the elements are operably linked (see figure 9).

Claims 1-3 lack an inventive step under PCT Article 33(3) as being obvious over Corbeau et al. (U.S. Patent No. 6,323,019) in view of Hope et al. (U.S. Patent No. 6,136,597).

Figure 8B of Corbeau et al. discloses a gene expression vector (pDM128) comprising a) an SV40 promoter, b) at least one splice donor site and at least one splice acceptor site, c) an expressible non-wild type sequence (i.e., CAT gene) located between the splice donor and splice acceptor, and d) an RRE from HIV, wherein the elements are operably linked (see figure 8B). Figure 8B also discloses the 3'-LTR.

Figure 8B of Corbeau et al. does not disclose a 5' HIV LTR. However, Corbeau et al. teaches that many promoters are useful, including known inducible and constitutive promoters. One preferred promoter comprises the 5' HIV LTR (see col. 4, lines 13-21). Other promoters that can be used include pol III promoters, pol II promoters, or the natural promoters found in an HIV LTR (see col. 6, lines 52-60). In addition, Hope et al. states that when cloning in mammalian cell systems, promoters derived from the genome of mammalian cells or from mammalian viruses (e.g., the retrovirus long terminal repeat; the adenovirus late promoter; the vaccinia virus 7.5K promoter) may be used (col. 13, lines 8-13). Thus, it would have been obvious to replace the SV40 promoter in figure 8B with the HIV 5'-LTR.

Claims 22 and 23 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest the sequences disclosed in SEQ ID Nos: 1-3.

Claims 1-3, 22 and 23 have industrial applicability as defined by PCT Article 33(4).

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## Supplemental Box Relating to Sequence Listing

## Continuation of Box No. I, item 2:

1. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this report was established on the basis of:

## a. type of material



a sequence listing



table(s) related to the sequence listing

## b. format of material



on paper



in electronic form

## c. time of filing/furnishing



contained in the international application as filed



filed together with the international application in electronic form



furnished subsequently to this Authority for the purposes of search and/or examination



received by this Authority as an amendment\* on \_\_\_\_\_

2. ☒ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

3. Additional comments:

\* If item 4 in Box No. I applies, the listing and/or table(s) related thereto, which form part of the basis of the report, may be marked "superseded."

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.  
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**Supplemental Box**

In case the space in any of the preceding boxes is not sufficient.

Continuation of:

**Section III. Non-establishment of report (description/claims/drawings unclear)**

Claims 4-19, 24-34 and 37-71 are dependent claims and are not drafted in accordance with PCT Rule 6.4(a).

Claims 2, 21, 35 ad 36 related to parts of the international application that do no comply with the prescribed requirements to such an extent that no meaningful international search can be carried out. Specifically, the claims make reference to non-identified accession numbers.